

**San Diego
Blood Bank**
Saving Lives Since 1950



0234 '02 MAY 16 P1:20

May 13, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 99D-5347: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Intimate Contacts, Draft Guidance, Center for Biologics Evaluation and Research (CBER)

To Whom It May Concern:

This letter is to comment on the Food and Drug Administration's proposed guidance *"Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Intimate Contacts."*

This guidance requires that all blood centers begin to ask blood donors questions regarding potential contact with xenotransplantation recipients. San Diego Blood Bank believes these questions to be unnecessary, and possibly adverse, in assuring the safest possible blood supply. Since xenotransplantation is extremely rare and most donors will not know what it is, the questions will be confusing to the vast majority of blood donors. The questions may very well detract from other high-risk questions that need to be answered honestly and thoughtfully by our potential blood donors.

The guidance also requires that close contacts of xenotransplantation recipients be deferred. We feel that this is an unnecessary deferral since the contacts are immuno-competent individuals who should not be at increased risk for zoonoses. Also, if this group of people were deferred, wouldn't the blood banking industry have to defer all types of people who work with animals?

Considering that xenotransplantation is a rare event, San Diego Blood Bank believes that the best course of action at this time would be to provide informational literature regarding this risk factor to all donors to read prior to the screening process. As such, the

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donor who is at risk can defer immediately and the screening process would not be burdened with additional questions.

We appreciate this opportunity to comment on FDA's notice "*Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Intimate Contacts.*"

If you have any questions, please feel free to contact Ms. Patricia Bakke, Director of Quality Assurance/Compliance, or me at 619-296-6393.

Sincerely,

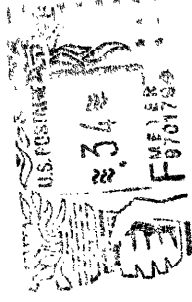
A handwritten signature in black ink, appearing to read "Ramona L. Walker". The signature is fluid and cursive, with the first name "Ramona" being more prominent.

Ramona L. Walker
Chief Executive Officer

lmd

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440 Upas Street
San Diego, California 92103-4900



DOCKETS MANAGEMENT BRANCH (HFA-305)
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE, ROOM 1061
ROCKVILLE, MD 20852

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